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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,914	09/10/2008	Xiu-Min Li	2005577-0010	6272
24280 7590 08/25/2009 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110				
EXAMINER HOFFMAN, SUSAN COE				
ART UNIT		PAPER NUMBER		
1655				
NOTIFICATION DATE		DELIVERY MODE		
08/25/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdoCKET@choate.com

Office Action Summary

Application No.

10/592,914

Applicant(s)

LI ET AL.

Examiner

Susan Coe Hoffman

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-11 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed July 30, 2009 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 2, 4, 12, 13 and 15 have been cancelled in this amendment.
3. Claims 1, 3, 5-11 and 14 are pending.

Claim Rejections - 35 USC § 103

4. Claims 1, 3, 5-8, 10, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson (WO 01/66122) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not provide any guidance to indicate that the specifically claimed composition would be effective to treat or lessen the severity of food allergy or anaphylactic shock. Applicant also argues that the reference does not specifically teach that each of the claimed ingredients is useful for treating allergies. However, page 6 of the reference specifically states that an herbal composition containing one or more of Ganoderma lucidum (Ling Zhi), Fructus Pruni Mume (Wu Mei), Pericarpium Zanthoxyli Bungeani (Chuan Jiao), Rhizoma Coptidis (Huang Lian), Cortex Phellodendri (Huang Bai), Rhizoma Zingiberis Officinalis (Gan Jiang), Ramulus Cinnamomi Cassiae (Gui Zhi), Radix Ginseng (Ren Shen), and Radix Angelicae Sinensis (Dang Gui) is useful in treating allergies. Since page 6 teaches that one or more of these ingredients is useful in treating allergies, the reference clearly teaches that each individual ingredient is useful in treating allergies. Thus, it would be obvious for an artisan to select any combination of these

ingredients because such a combination is specifically within what is taught in the reference. As discussed in *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007):

A person of ordinary skill in the art is also a person of ordinary creativity, and not an automaton...When there is a design need of market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Combining ingredients known to be useful for the same purpose is considered to be an obvious modification of the prior art. The artisan would predict that the composition composed of the individual ingredients would be useful for the same purpose as the individual ingredients. Thus, selection of specific ingredients from the reference is not considered to be inventive.

In addition, applicant argues that the current specification shows that each of the individual components reduce anaphylaxis to the degree shown by the combination of the claimed ingredients, i.e. the FAHF-2 product. The applicant points out Example 8, Table 4 to support this assertion. Applicant also has supplied Kattan (Phytotherapy Research (2008), vol. 22, pp. 651-659) to show that the FAHF-2 functions more effectively than a combination of *Phellodendron chinense* (Huang Bai), *Ganoderma lucidum* (Ling Zhi) and *Zingiber officinalis* (Gan Jiang). However, this evidence of unexpected results is not considered to render the claimed invention patentable over the prior art because the unexpected results are not commensurate in scope with the claimed invention (see MPEP 716.02(d)). Table 1 in applicant's specification describes the ingredients in FAHF-2. This table shows that FAHF-2 contains specific amounts of each ingredient. Kattan also teaches that FAHF-2 is made with specific amounts (see Table 1). Applicant's current claims are not limited to a particular amount of each

ingredient. Thus, applicant's showing of unexpected results is not commensurate in scope with the claimed invention. Therefore, the claims are not considered to be allowable based on unexpected results.

5. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson as applied to claims 1, 3, 5-8, 10, 11 and 14 above, and further in view of prior art admitted by applicant in the specification for the reasons set forth in the previous Office action.

Applicant argues that the prior art admitted in the specification does not cure the deficiencies of Sampson. However, Sampson is not considered to be deficient for the reasons discussed above.

6. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655